

Amendments to the Drawings

Enclosed herewith are corrected drawings consisting of a new sheet depicting Fig. 1, Fig. 1A and new Fig. 1B, and a replacement sheet depicting Fig. 5a and Fig. 5b. Delivery Device 1 is now identified in Figs. 1A and 1B. Compartments 26a through 26e are now also identified in the Replacement Sheet depicting Figs. 5a and 5b. Fig. 1B shows the delivery device 1 inserted into the eye through an incision until the rim of cap 8 abuts the incision.

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Application No. 10/823,089

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Docket No.: 56086CON2(71699)

REMARKS

Claims 82-91 and 103-114 are pending. Claims 82, 87, 91, 106, 109, and 112-114 are amended. Support for the amendments is found throughout the specification as originally filed, and no new matter is added. Reconsideration of the application is respectfully requested.

1. Oath/Declaration

The Examiner has requested a new oath or declaration, because currently it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Applicants will submit the new declaration to the Patent Office in due course.

2. Drawings

The Examiner objects to the drawings for failing to include reference signs 1, 26c, 26d, and 26e. Enclosed herewith are corrected drawings consisting of a new sheet depicting Fig. 1, Fig. 1A and new Fig. 1B, and a replacement sheet depicting Fig. 5a and Fig. 5b. Delivery device 1 is now identified in Figs. 1A and 1B. Compartments 26a through 26e are now also identified in the Replacement Sheet depicting Figs. 5a and 5b.

3. Specification

The Office objects to the Title as not being descriptive. Applicants have amended the Title herein as requested.

Applicants have further amended the abstract to correct typographical errors, as requested. As requested, paragraph 1 of the specification has been amended to set forth corresponding issued U.S. Patent No. 6,719,750. In addition, the Office's attention is directed to related co-pending U.S. patent application no. 10/823,089, currently under a non-final Office Action. The specification has further been amended to include brief descriptions of Figs. 1a, 4b-1, 4c-1, 4d-1, 4d-2 and 5c.

The Office asserts that the "specification fails to disclose the method with the step of inserting into a patient ear the device, where the device is inserted into the ear through an incision until the cap member abuts the incision, and where the cap member remains outside the incision and the body member resides in the patient ear." The Office further asserts that

the specification "fails to disclose the method with the step of inserting the device through an incision in a patient ear by twisting or screwing the coil-shaped member in through the incision until the cap member abuts the outside of the incision, and where the body member resides in the patient ear." Applicants respectfully traverse this objection.

Insertion of the device is set forth in the specification in connection with ocular insertion and drug delivery. In particular, it is set out that "[t]he delivery device may further include a rim or cap at its proximal end. During use, the device is inserted into the eye through an incision until the rim or cap abuts the incision" (see [0014] and [0044] of U.S. Publication No. 2005-0059956). As further set forth "the coil shape of the body member allows the device to be screwed or twisted into the eye through an incision approximately the same size as the outer diameter of the tube forming the body member 2" (see [0037] of U.S. Publication No. 2005-0059956). As clearly disclosed in the specification, "[t]he invention is not be limited to ocular applications, and is particularly useful in other limited access regions such as the inner ear." (see [0075] of U.S. Publication No. 2005-0059956)

Thus, it is respectfully submitted that the claimed use of the device is clearly supported by the specification. Reconsideration and withdrawal of the rejection is respectfully requested.

4. Claim Objections

Claims 91, 106, 109, and 112-114 are objected to for reciting limitations having insufficient antecedent basis. Applicants have amended the claims as requested.

5. 35 U.S.C. §102 Rejections

Kelley et al.

Claims 82-89, 103-109, and 112-114 are rejected under 35 U.S.C. §102(b) over U.S. Patent No. 4,701,180 to Kelly et al. (hereinafter "Kelly"). Applicants respectfully traverse.

Applicants recite, in independent claim 82, a method for treating a patient comprising (a) providing a delivery device comprising a body member having a helical or zig-zag shape and a cap member that abuts an incision through which the device is inserted to stabilize the device once implanted, and (b) inserting into a patient ear the device, whereby the device is inserted into the ear through an incision until the cap member abuts the incision, and wherein

the cap member remains outside the incision and the body member resides in the patient ear and a therapeutic substance is administered to the patient via the body member.

Applicants recite, in independent claim 103, a method for treating a patient comprising (a) providing a delivery device comprising a therapeutic substance and a coil-shaped body member having at least two deviations from a linear path and a cap member that abuts an incision through which the device is inserted to stabilize the device once implanted; and (b) inserting the device through an incision in a patient ear by twisting or screwing the coil-shaped body member in through the incision until the cap member abuts the outside of the incision, whereby the body member resides in the patient ear and the therapeutic substance is administered to the patient via the body member.

Kelly describes a device for implantation behind an animals' ear. The device includes an anchor 10 and an insert 12, wherein the insert 12 is inserted within and held in place by the anchor 10 (see, e.g., col. 3, lines 21-24). In particular, the anchor comprises an anchor flange 14 and a sleeve 16 in which the insert 12 is held. The sleeve 16 has internal threads 18 disposed around its interior surface which engage corresponding external threads 62 disposed about the outer surface of the insert (see, e.g. col. 3, lines 41-43; col. 4, lines 6-16; col. 6, lines 42-50; Fig. 3).

Thus, Kelly clearly does not teach or suggest a delivery device or method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member. Rather, Kelly's implantation device includes an anchor and insert with corresponding mating threads that are internal to the device, and which are provided for holding the anchor in place within the insert. As clearly shown and described, Kelly's device is devoid of a helical, coil, or zig-zag shaped body member for disposal within the eye and for administration of a therapeutic substance (see Fig. 1).

In view thereof, it is respectfully submitted that claims 82 and 103 are not anticipated by Kelly. Claims 83-89, 104-109, and 112-114 depend from claims 82 and 103 and, thus, also are not anticipated by Kelly. Reconsideration and withdrawal of the rejection is respectfully requested.

6. 35 U.S.C. §103 Rejections

Kelly and Johnson

Claim 90 is rejected under 35 U.S.C. §103(a) over Kelly and U.S. Patent No. 5,972,027 to Johnson (hereinafter "Johnson"). Applicants respectfully traverse.

As set forth above, Kelly at least fails to teach or suggest a delivery device and method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member.

Johnson does not remedy these deficiencies. Johnson is cited for describing the use of nitinol (a shape memory material) in forming implants. However, Johnson, like Kelly, at least fails to teach or suggest a delivery device and method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member.

In view thereof, it is respectfully submitted that claim 82 is patentable over Kelly and Johnson. Claim 90 depends from claim 82 and, thus, also is patentable over Kelly and Johnson. Reconsideration and withdrawal of the rejection is respectfully requested.

Kelly and Rosenwald

Claim 91 is rejected under 35 U.S.C. §103(a) over Kelly and U.S. Patent No. 4,678,466 to Rosenwald (hereinafter "Rosenwald"). Applicants respectfully traverse.

As set forth above, Kelly at least fails to teach or suggest a delivery device and method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member.

Rosenwald does not remedy these deficiencies. Rosenwald is cited for describing the use of a device being 1.5 cm or less in length. However, Rosenwald, like Kelly, at least fails to teach or suggest a delivery device and method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member.

In view thereof, it is respectfully submitted that claim 82 is patentable over Kelly and Rosenwald. Claim 91 depends from claim 82 and, thus, also is patentable over Kelly and Rosenwald. Reconsideration and withdrawal of the rejection is respectfully requested.

Kelly and Bowman

Claims 110 and 111 are rejected under 35 U.S.C. §103(a) over Kelly and U.S. Patent No. 6,397,849 to Bowman (hereinafter "Bowman"). Applicants respectfully traverse.

As set forth above, Kelly at least fails to teach or suggest a delivery device and method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member.

Bowman does not remedy these deficiencies. Bowman is cited for describing the use of a biodegradable polymer for use in implants. However, Bowman, like Kelly, at least fails to teach or suggest a delivery device and method for treating a patient using a delivery device by inserting into the ear a device comprising a body member having a helical, coil, or zig-zag shape, whereby the body member resides in the patient ear and therapeutic substance is administered to the patient via the body member.

In view thereof, it is respectfully submitted that claim 82 is patentable over Kelly and Bowman. Claims 110 and 111 depend from claim 82 and, thus, also are patentable over Kelly and Bowman. Reconsideration and withdrawal of the rejection is respectfully requested.

7. Double Patenting

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Claims 82-91 and 103—114 are provisionally rejected as being unpatentable over claims 83-110 and 117-120 of copending Application No. 10/740,698.

Applicant will address the double patenting rejections upon a finding that the claims (that will be pending upon entry of the amendments presented herein) are in condition for allowance, but for the instant double patenting rejections.

CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

If for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Office is hereby authorized and requested to charge Deposit Account No. 04-1105.

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Respectfully submitted,

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